IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	: : : :	MDL DOCKET NO. 1203

PRETRIAL MEMORANDUM AND ORDER NO.

BECHTLE, J. OCTOBER , 2000

Presently before the court is the Plaintiffs Management Committee's ("PMC") Motion for an Order Compelling the United States Food and Drug Administration ("FDA") to Produce Certain Documents; the United States' Memorandum of Law in Opposition thereto and the PMC's Reply to the United States' Memorandum of Law in Opposition. For the reasons set forth below, the court will grant the motion in part and deny the motion in part.

I. BACKGROUND

The PMC seeks to compel production of 132 documents withheld by the FDA from discovery on the basis of the deliberative process privilege and/or the attorney-client privilege. (PMC's Mot. for an Order Compelling the FDA to Produc. Certain Docs. ("Mot. to Compel") at 1.) The PMC's discovery requests were made through subpoenas and the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Id. at 12-13 & Ex. H. The documents requested relate to whether the FDA was in possession of certain documents concerning potential detrimental effects of diet drugs on the heart.

The PMC is the steering committee appointed by the court to oversee the conduct of consolidated/coordinated pretrial proceedings on behalf of plaintiffs who allege that they have suffered, inter alia, heart valvulopathy from the ingestion of the diet drugs at issue in this case. (Pretrial Order No. 6.)

In May 1999, six FDA officials authored an article in the Journal of the American Medical Association ("JAMA") in which they indicated that at the time the FDA approved the drugs, neither the FDA, the manufacturers nor the medical community had reason to believe that they were potentially associated with heart valvulopathy. (Mot. to Compel Ex. A.) One of the defendants in this litigation, American Home Products Corporation ("AHP"), began to use this article in its defense (the "FDA defense"), arguing that it acted reasonably in distributing its product based upon information available at the time. Id. at 3.

Seeking information to refute the FDA defense, the PMC attempted to depose each of the JAMA article's authors, but the FDA refused the PMC's requests as to five of them. (United States' Mem. of Law in Opp'n ("Mem. in Opp'n") at 2.) In its June 4, 1999 letter requesting these depositions, the PMC noted that certain information about the health effects of the diet drugs was available to AHP before March 1997, including: medical literature indicating cardiotoxic effects of fenfluramine, a dexfenfluramine toxicology study showing fibrosis in the hearts of rats and 105 reports of heart valvulopathy received by drug manufacturers. (Mot. to Compel at 7-8.) The PMC alleged that

AHP withheld this information from the FDA. Id. at 8. The FDA responded on July 21, 1999 with a letter stating that at the time the JAMA article was published, to the best of its knowledge, the FDA was not in possession of this health effects information. Id. at 8 & Ex. D. The one author who was deposed by the PMC, Jeffrey E. Shuren, M.D., indicated that he was unaware of this information when the article was written. Id. at 9.

On August 3, 1999, the FDA received a letter from AHP's counsel, William Vodra, indicating that AHP had provided this health effects information to the FDA before the article was published. Id. at 10 and Ex. G. After reviewing its records, the FDA wrote the PMC on October 5, 1999 confirming that it was in possession of much of this information at the time of the article's publication and listing the documents that it possessed. Id. at 10-11. The PMC responded on October 12, 1999 by demanding answers to the following questions: 1) why were the JAMA article's authors unaware of this information?; 2) what investigation did the FDA make before stating in the July 21, 1999 letter that it was unaware of this information?; 3) did AHP fail to appropriately bring this information to the FDA's attention?; 4) in light of this information, did the authors reevaluate the representations made in the JAMA article and 5) if so, what did they conclude? Id. at 11-12 & Ex. H. The PMC also requested further discovery, including production of documents related to the PMC's letter of June 4, 1999; the FDA's letters of July 21 and October 5, 1999 and William Vodra's August 3, 1999

letter to the FDA. Id.

The FDA, through its Associate Chief Counsel for Enforcement, provided documents in response to the PMC's requests along with the Privilege Log describing the 132 withheld documents that are the subject of this motion. Id. at 13-15 & Ex. I; Mem. in Opp'n at 2.

II. STANDARD OF REVIEW

The FDA asserts that its decision not to produce the 132 documents on the basis of privilege must be reviewed under the "arbitrary and capricious" standard of the Administrative Procedures Act ("APA"), 5 U.S.C. § 706. (Mem. in Opp'n at 3.) Conversely, the PMC argues that because the discovery requests were made through subpoenas and FOIA, the FDA's privilege claims can only be reviewed under Exemption 5 of FOIA or Federal Rule of Civil Procedure 45.[1] Reply to Mem. in Opp'n at 6-7; see Mot. to

[1] There is a split of authority as to whether a non-party federal agency's decision not to comply with federal subpoenas is reviewed pursuant to the APA's "arbitrary and capricious" standard or de novo under the court's discretionary right to limit burdensome discovery under the Federal Rules of Civil Procedure. Compare Comsat Corp. v. Nat'l Sci. Found., 190 F.3d 269, 277 (4th Cir. 1999) (stating that "[w]hen the government is not a party, the APA provides the sole avenue for review of an agency's refusal . . . to comply with subpoenas.") and Davis Enters. v. United States Envtl. Prot. Agency, 877 F.2d 1181, 1186 (3d Cir. 1989) (reviewing EPA's refusal to comply with subpoena under arbitrary and capricious standard) with Exxon Shipping Co. v. United States Dept. of Interior, 34 F.3d 774, 778-79 (9th Cir. 1994) (holding that federal rules of discovery apply to discovery request made against federal agency, whether or not United States is party); see generally 5 U.S.C. § 706 (setting out standard of review under APA); Fed. R. Civ. Pro. 26 & 45 (delineating court's power to limit discovery). These cases do not address requests

Compel Ex. H at 3 (requesting disputed documents pursuant to FOIA and subpoena).

The court agrees with the PMC, and will review de novo the FDA's denial of the FOIA request.[2] The court is not reviewing the quality of the FDA's decision making with regard to matters within its expertise, but rather the application of a general federal statute that is unrelated to the FDA's mandate of ensuring the safety of food, drugs and medical devices.

In determining the applicability of a FOIA exemption, "the agency's opinion carries no more weight" than the opinions of others before the court. Mead Data Cent. Inc., v. Dep't of the Air Force, 566 F.2d 242, 252 (D.C.Cir. 1977). The district court "shall determine the matter de novo, and may examine the . . . records in camera." 5 U.S.C. § 552(a)(4)(B); Lame v. United States Dep't of Justice, 654 F.2d 917, 921 (3d Cir. 1981); Manna v. United States Dep't of Justice, 832 F. Supp. 866, 870 (D.N.J. 1993). The burden is on the agency to justify its refusal to

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for production under FOIA.

[2] At a status conference held February 10, 2000, counsel for the FDA argued that FOIA was inapplicable because the PMC had not formally instituted suit against the FDA under FOIA. (Tr. 2/10/00 at 87-88.) The FDA did not raise this argument in its Response to the PMC's motion. Neither party has cited authority indicating whether such a formal suit is necessary or whether a request alone is adequate, or whether enforcement of a subpoena requesting documents under FOIA constitutes a formal proceeding sufficient for the court to decide the issue. The court believes that the subpoena is sufficient to bring the issue before the court for decision. To require a formal suit under FOIA would create needless delay and expense only to bring the same issue before the court at a later time.

disclose. 5 U.S.C. § 552(a)(4)(B); Lame, 654 F.2d at 921.

II. DISCUSSION

FOIA exempts from disclosure, inter alia, "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5). This exemption extends to documents that are traditionally privileged from discovery, including the "deliberative process" privilege and the attorney-client privilege. Schlefer v. United States, 702 F.2d 233, 237 (D.C.Cir. 1983). FOIA exemptions are read narrowly and disputes regarding Exemption 5 are resolved by rough analogy to the rules of discovery. Mead Data, 566 F.2d at 252. "Conclusory assumptions of privilege will not suffice to carry the government's burden of proof in defending FOIA cases." Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 861 (D.C. Cir. 1980). Rather, the agency must provide "a relatively detailed justification, specifically identifying the reasons why a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply." Mead Data, 566 F.2d at 251 (citations omitted); see also In re Unysis Corp. Retiree Med. Benefits ERISA Litig., No. MDL 969, 1994 WL 6883, *2 (E.D. Pa. Jan. 6, 1994) (citing Bowne v. Ambase Corp., 150 F.R.D. 465 (S.D.N.Y. 1993)) (holding that list containing date, author, addresses, type of document, skeletal description of subject and privilege claimed was inadequate to

invoke attorney-client privilege).

The Privilege Log submitted by the FDA in lieu of producing the 132 documents at issue is insufficient to prove the applicability of Exemption 5. The limited information disclosed in the Privilege Log is nearly identical to the information submitted to the court in Coastal States, another FOIA case. Coastal States, 617 F.2d at 861. In that case, the privilege log identified the author of the document, the person to whom it was addressed and a brief description of the memorandum.[3] Id. Similarly, FDA's privilege log identifies only the author, the person to whom it was addressed, the date, the type of document (e.g., e-mail) and a brief description of the memorandum such as "FDA's possession of documents." (Mot. to Compel Ex. I.) Like the courts in Coastal States and In re Unysis, the court finds that "such an index is patently inadequate to permit a court to decide whether the exemption was properly claimed." Coastal States, 617 F.2d at 861; In re Unysis, 1994 WL 6883, at *2-3. Accordingly, the court has conducted in camera review of the withheld documents and concludes that there is insufficient proof of the applicability of the deliberative process privilege to any of the documents, but that the attorney-client privilege applies to all of the documents for which it was invoked.

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[3] The following is an example of a description given in the Coastal States log: "Advice on audit of reseller whether product costs can include imported freight charges, discounts, or rental fees. Sections 212.93 and 212.92." Coastal States, 617 F.2d at 861.

A. The Deliberative Process Privilege

The deliberative process privilege encompasses "confidential deliberations of law or policy-making, reflecting opinions, recommendations, or advice." Redland Soccer Club, Inc. v. Dep't of the Army, 55 F.3d 827, 853 (3d Cir. 1995) (citations omitted). Its purpose is to "prevent injury to the quality of agency decisions." N.L.R.B. v. Sears Roebuck and Co., 421 U.S. 132, 151 (1975); Redland Soccer, 55 F.3d at 854. The privilege does not protect factual information that is severable from an otherwise protectable document, nor does it protect "[c]ommunications made subsequent to an agency decision." Id. (citing In re Grand Jury, 821 F.2d 946, 959 (3d Cir. 1987), and quoting United States v. Farley, 11 F.3d 1385, 1389 (7th Cir. 1993)).

The government must demonstrate the applicability of the privilege. Id. Two critical factors in determining the applicability of the privilege are whether the document is "predecisional" (i.e. created before adoption of the agency policy) and whether it is "deliberative" (i.e. reflects the give and take of the consultive process). Coastal States, 617 F.2d at 866.

If the court determines that the privilege applies, it must balance the relative interests of the parties, with the party seeking discovery bearing the burden of showing that its need outweighs the government's interest. Redland Soccer, 55 F.3d at 854. When balancing interests, the court should consider, at a minimum, the:

i) relevance of the information sought to be protected;

ii) availability of other evidence;

iii) seriousness of the litigation and the issue involved;

iv) role of the government in the litigation; and

v) possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

Id. at 854 (quoting First E. Corp. v. Mainwaring, 21 F.3d 465, 468 n.5 (D.C. Cir. 1994)).

The parties differ in their identification of the agency action relevant to the privilege. The PMC asserts that publication of the JAMA article is the agency action at issue, and that therefore the privilege is inapplicable because the documents reflect "post-decisional" communications. The FDA asserts that the responses to letters from the PMC and Vodra are the agency action at issue.

The court concludes that the deliberative process privilege is inapplicable to the documents withheld by the FDA. There is little in the nature of these documents that can be considered deliberation over agency policy. Rather, the documents withheld on the basis of the deliberative process privilege contain communications concerning whether the FDA possessed certain documents, what those documents were and who they were being sent to within the agency.[4] First, these documents reflect largely

[4] Representative of the documents withheld on the basis of deliberative process privilege is an e-mail from one FDA

factual information. Second, contrary to the FDA's assertion, its responses to the PMC's FOIA requests are not discretionary agency actions or policies for purposes of the deliberative process privilege. Third, the FDA has not demonstrated why formulating a response to the letter from AHP's counsel should be considered an agency policy for purposes of the deliberative process privilege. Thus the internal deliberations preparatory to the FDA's responses are not "the sort of internal communications that the deliberative process privilege was intended to protect." See Mem. in Opp'n at 7-8 (asserting that deliberations concerning the FDA's July 21 and October 5, 1999 letters are privileged). The court need not engage in a balancing of interests as the FDA has not demonstrated the applicability of the privilege. Accordingly, to the extent that the PMC seeks to compel production of documents withheld on the basis of the deliberative process privilege, its motion will be granted.

B. The Attorney-Client Privilege

The attorney-client privilege protects confidential communications between a lawyer and client made for the purpose of securing or conveying legal advice. See generally Rhone-Polenc Rhorer, Inc. v. Home Indem. Co., 32 F.3d 851, 862-63 (3d Cir. 1994). The privilege applies if the following elements are

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official requesting that another official check for certain document numbers and provide copies of those documents if they are found.

shown: (1) the asserted holder of the privilege is or sought to become a client; (2) the person to whom the communication was made (a) is a member of a bar of a court, or his or her subordinate, and (b) in connection with this communication is acting as a lawyer; (3) the communication relates to a fact of which the attorney was informed (a) by a client (b) without the presence of strangers (c) for the purpose of securing primarily either (i) an opinion of law or (ii) legal services or (iii) assistance in some legal proceeding, and (d) not for the purpose of committing a crime or tort; and (4) the privilege has been (a) claimed and (b) not waived by the client. Id. at 862. The privilege extends to agency officials who are authorized to speak for the agency in regard to the subject matter of the communication. Mead Data, 566 F.2d at 253. Where the record is ambiguous as to the applicability of the privilege, the party asserting it must show "by record evidence such as affidavits, sufficient facts to bring the communications at issue within the narrow confines of the privilege." In re Sunrise Sec. Litig., 130 F.R.D. 560, 570 (E.D. Pa. 1989).

Communications between FDA officials and FDA attorneys made in connection with formulating responses to subpoenas and letters from the PMC, and the letter from AHP's counsel, are privileged. All of the documents withheld from disclosure by the FDA on the basis of attorney-client privilege contain communications between an FDA official and an FDA attorney. It appears that these communications were intended to be confidential, as evidenced by

the fact that many are marked with the terms "Sensitivity: Confidential." The communications were apparently only accessible to persons within the agency who were aiding FDA counsel by gathering information necessary to make those responses, thus they were confidential. While the underlying facts discussed in these communications may not be privileged, the communications themselves are privileged.[5] Formulating a response to requests for documents is clearly a legal service rendered by FDA attorneys. Lastly the FDA has invoked the attorney-client privilege, and there is nothing to indicate that the privilege has been waived as to these communications. Accordingly, the motion will be denied with regard to the documents withheld on the basis of attorney-client privilege.[6]

IV. CONCLUSION

For the reasons set forth above, the PMC's motion will be

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[5] As noted in its Opposition, the FDA has disclosed the underlying facts regarding what knowledge was in the possession of FDA officials at the time of the JAMA article's publication. (Mem. in Opp'n at 11.)

[6] Some of the documents and communications which are entitled to protection under the attorney-client privilege have also been reproduced in communications between FDA officials who are not attorneys. When reproduced in such communications, they are not privileged because they were not communicated to an attorney. Furthermore, even if the FDA officials were communicating with each other under the direction of their attorneys, the attorney-client privilege was not invoked to protect those documents. As discussed above, such documents are not protected under the deliberative process privilege because responding to requests for documents is not an agency action to which that privilege applies.

granted in part and denied in part. An appropriate order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	: : : :	MDL DOCKET NO. 1203

PRETRIAL ORDER NO.

AND NOW, TO WIT, this day of October, 2000, upon consideration of the Plaintiffs Management Committee's Motion for an Order Compelling the United States Food and Drug Administration to Produce Certain Documents; the United States' Memorandum of Law in Opposition thereto and the PMC's Reply to the United States' Memorandum of Law in Opposition, IT IS ORDERED that said motion is GRANTED as to all documents withheld solely on the basis of deliberative process privilege, and DENIED as to all documents withheld on the basis of attorney-client privilege.

LOUIS C. BECHTLE, J.